Spot On Sciences, Inc. 4/12/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Warning Letter

April 12, 2016

Jeanette Hill, Ph.D.
CEO and Quality Assurance
Spot On Sciences
8204 N. Lamar Blvd. Suite C17
Austin, TX 78753

Re: Spot On Sciences HemaSpot Dried Blood Spot Collection line of products.
Refer to CTS Document Number CMS487059

Dear Dr. Hill:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing HemaSpot Blood Collection line of products, dried blood spot collection devices, in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The Office of *In Vitro* Diagnostics and Radiological Health (OIR) in the Center for Devices and Radiological Health (CDRH) learned of this marketing when reviewing your firm's website,

www.spotonsciences.com, as well as www.elevatemyhealth.com which is linked from your www.spotonsciences.com website.

Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

The HemSpot Blood Collection device and the HemaSpot SE device are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the devices as described and marketed. These devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution these devices without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Specifically:

> Per telecon with your firm on April 24th, 2014, FDA/CDRH/OIR outlined three options for your firm to ensure it is in compliance with FDA laws and regulations concerning its blood collection devices. These included: submit a 510(k) for the devices, label the devices as research use only (RUO), or label the devices for investigational use only.
>
> Your firm agreed to bring labeling into compliance with 21 CFR 809.10(c)(2)(i) by May 29th, 2014 and implement a “certification program” where users certify they will not use the product other than for research use only. Your firm also agreed to completely remove claims on its website that are not in accordance with the RUO designation and that changes were to be made before June 11th, 2015.

Additionally, your firm states on its website, www.spotonsciences.com as well as in correspondence provided to FDA/CDRH/OIR on April 25th, 2014 that the HemaSpot collection devices are intended for research use only, not for use in diagnostic procedures. However, your firm’s www.spotonsciences.com website has a press release dated March 10th, 2014 which has information that your firm has partnered with CoreMedica laboratories to provide direct-to-consumer diagnostic testing for various medical conditions using your HemaSpot blood collection devices. The press release has a link to the website www.elevatemyhealth.com. Clicking on the www.ElevateMyHealth.com link takes a user directly to the Elevate My Health website where the collection devices can be ordered direct to consumer through an online

payment service.

Additionally statements on the websites identified above indicate that the dried blood spot collection devices are intended to be used in diagnostic testing. Statements to that effect include, but are not limited to, the follow:

- "'Teaming with CoreMedica brings together the ease and simplicity of collecting a blood sample with a quality test you can depend on,' said Dr. Jeanette Hill, founder and CEO of Spot On Sciences. 'By allowing anyone to take a blood sample anywhere and at any time gives people the freedom to track their personal health'." (http://www.spotonsciences.com/news/coremedica-and-spot-on-sciences-launch-new-site-for-home-based-blood-tests/)
- "Spot On Sciences, Inc. develops and markets innovative devices that revolutionize collection and storage of biological fluids for medical research and testing. Based in Austin, TX, initial products, HemaForm™ and HemaSpot™, enable remote collection of blood samples offering solutions for multiple markets including clinical trials, biobanking, home-based wellness testing, military field medicine and population studies." (http://www.spotonsciences.com/background/)
- "By enabling remote blood sampling, HemaSpot™ has many applications for health and medical research. We've been talking to experts in the field and the accolades are accumulating. In the words of a cardiovascular medical doctor, HemaSpot™ will "…completely change the way clinical science is performed." A medical association officer has this to say: "HemaSpot™ will revolutionize blood sampling." (http://www.spotonsciences.com/hemaspot/)
- "Value: Greatly increase access to medical testing for chronic diseases and reduce health disparities for underserved and resource-limited populations. People who are home-bound or live in remote and rural areas sometimes lack transportation for routine medical screening. In addition, there are those who cannot take time off from work, finding it difficult to travel to a lab in order to have their blood drawn. HemaSpot™ makes it possible for individuals to take their own sample with a finger stick, whether at home or at work, and mail the sample to the testing lab. This simple collection method could vastly improve access to medical testing for resource-scarce environments and underserved populations in both developed and developing nations including remote, home-bound and socioeconomically disadvantaged patients." (http://www.spotonsciences.com/applications/)
- "Nothing's more important than good health and checking your status should be on everyone's "To-Do" list. We offer the convenience and privacy of at home collection together with the reliability and accuracy from a professional and nationally accredited laboratory to stay informed on your current state of health." (https://www.elevatemyhealth.com/)
- "OUR MISSION To provide individuals the power to be informed about their health in a safe, convenient, and less-invasive environment through access to basic

clinical laboratory tests for health awareness and disease management." (https://www.elevatemyhealth.com/)

- "HemaSpot & HemaSpot SE is an easy to use device that allows anyone to collect a blood sample from anywhere and at any time. Our collection kit includes all the supplies to correctly collect your sample for laboratory analysis. A postage-paid return envelop is provided." (https://www.elevatemyhealth.com/dbs-collection.html)
- "Analyses are performed by experienced medical scientists using state-of-the-art robotic instrumentation under strict quality standards to ensure accurate and reliable results. Results are reported within 24-36 hours of receipt and released in a comprehensive interpretative report for individuals seeking basic medical information about their current state of health." (https://www.elevatemyhealth.com/reliable-results.html)

Our office requests that Spot On Sciences immediately cease activities that result in the adulteration and misbranding of the HemaSpot Blood Collection device and HemaSpot SE device, such as the commercial distribution of the devices for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
The Office of *In Vitro* Diagnostics and Radiological Health
Attention: James Woods, Deputy Director Product Safety and Product Quality
White Oak Building 66, Rm4684

10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS487059when replying. We remind you that only written communications are considered official. If you have any questions about contents of this letter, please contact Ileana Elder at (301) 796-6143.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely,
/S/
Alberto Gutierrez, Ph.D.
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

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